Executive Summary

Precision Predictive Analytics
Non-Invasive Lung Cancer Risk Stratification

ProLung's mission is to make a difference in time for lung cancer patients who face an under-prioritized and highly stigmatized disease. Lung cancer is the leading cause of cancer deaths worldwide, killing more than colorectal, breast, pancreatic and prostate cancers combined. There is a severe unmet clinical need to reduce the time required to determine malignancy in patients diagnosed with Indeterminate Pulmonary Nodules (IPNs). Patients with IPNs wait months, or even years, receiving multiple CT scans to confirm malignancy in the lungs. This wait often proves fatal as the cancer advances and spreads. In 2015, the US Preventive Services Task Force and Centers for Medicare and Medicaid Services (CMS) implemented the first national lung cancer screen utilizing a low-dose CT scan (LDCT) of the chest. The screen will amplify this clinical need as it identifies up to 24 million patients with IPNs who will experience a narrowing treatment window as they wait.

ProLung addresses this need at a critical time with its breakthrough predictive analytics test, The ProLung Test™. The test uses precision proprietary *volume-averaging bioconductive technology* to collect bioconductance data in patients with IPNs. The data is analyzed to produce a personalized score indicating the likelihood of malignancy in the lungs. The wait can be reduced from months and years to one day. Patients at high-risk may be accelerated to biopsy and diagnosis, expanding the therapeutic window. Patients at low-risk may avoid futile biopsies and justify fewer follow-up CT scans. The test is non-invasive, non-radiating, rapid and accurate. ProLung's predictive and personalized approach to early detection is a significant step forward in the management and treatment of lung cancer. The ProLung Test will add efficiency to the LDCT screen and create significant cost savings for CMS. The ProLung Test is available in Europe and in use at cancer centers in Italy and Switzerland. The company is anticipating US FDA approval with its pivotal work at 15 premier US cancer centers.

Unmet Clinical Need in Lung Cancer

Lung cancer has the lowest five-year survival rate of all major cancers, at approximately 16 percent[1]. It is now the leading cause of cancer death in women as well as men. The disease remains the most common cancer in men worldwide[2]. There are estimated to have been 1.8 million new cases globally in 2012. In the United States, according to the American Cancer Society, 224,390 new cases of lung cancer are estimated in 2016 with 158,080 disease-related deaths resulting from tobacco use, exposure to secondhand smoke, radon, asbestos and other risk factors[3].

There is often a delay in the standard of care between the time of discovery of an IPN and the official diagnosis. Discovery of an IPN is immediate either through an incidental finding or CT screen. Diagnosis can require one day following a surgical biopsy. A period of risk stratification is required for the physician to determine with a high degree of certainty that the IPN is likely malignant and warrants a dangerous and invasive biopsy. This waiting time can take months or even years and repeated CT screens to identify growth in the nodule that is suspicious for cancer. The chance to diagnose and treat a malignant nodule in its early, localized state is often lost. If lung cancer is diagnosed while localized at an early stage, five-year survival rates may soar to over 50 percent[4].

Elegant Solution through Predictive Analytics

ProLung's predictive clinical analytics device immediately evaluates IPNs that have been identified by CT scan and provides an accurate assessment of the risk of malignancy in the lungs. Patients with a high probability of malignancy may be prioritized for biopsy, leading to an earlier diagnosis with improved prognosis and treatment options. Pre-surgical evaluation may also improve outcomes for individuals with benign nodules through a reduction in futile biopsies which involve significant risk (4.4% mortality rate for resection by thoracotomy, possible pneumothorax and infection), a relaxed CT vigilance program and decreased emotional trauma.

Results published in the *Journal of Thoracic Oncology* and performed at Johns Hopkins School of Medicine yielded 92% specificity and 90% sensitivity in subjects with one or more indeterminate lung masses, confirmed by tissue biopsy. Other published research demonstrates superior performance in the evaluation of these patients in comparison to FDG PET scans. Further testing of the accuracy and safety of the ProLung Test is underway at multiple sites: MD Anderson Cancer Center, Huntsman Cancer Institute, Intermountain Healthcare, Henry Ford Hospital, Greater Baltimore Medical Center, Stanford, UCLA, UCSD, Providence Healthcare Network, Loyola University and the Mayo Clinic among others.

One Billion Person Global Market

There are an estimated one billion people at high-risk for lung cancer worldwide. ProLung is in the process of launching its ProLung Test in the largest at-risk global populations (US, Europe, Middle East and China). China alone consumes one in every three cigarettes smoked in the world and has a high-risk population of over 550 million people. Clinical testing is underway at multiple academic institutions in China including Zhongshan Hospital, Nantong Tumor Hospital, Shanghai Pulmonary Hospital and Shanghai East Hospital.

The ProLung System is CE marked and available in Europe. The ProLung Test is currently in commercial and investigational use at multiple sites across Italy and Switzerland. Over 200 patients have been scanned in Europe with more than 150 of them enrolled in ProLung's European Patient Registry.

Recurring Revenue Model

The ProLung Test is sold using a recurring sales model similar to pathology testing laboratories. The ProLung System will be sold to hospitals, clinics and diagnostic centers for minimal capital outlay with an aim to build a large installed base. The ProLung Test Kit™, containing the disposables and unique test identifier is estimated to produce 90% of projected sales in the form of recurring revenue with operating margins well above 50%.

Regulatory and Manufacturing Approvals

The ProLung System is CE marked as a category II device (certificate 13/82829), a designation recognized by regulatory authorities in many international markets. It is manufactured by ProLung under an ISO 13485 certified Quality Management System (certificate US 13/82775), with fully automated real-time component traceability, product assembly, risk management and product reliability testing. US FDA regulatory approval is via a 510(k) de novo application and is anticipated in 2017.

Intellectual Property Portfolio

ProLung's four issued US patents (and related foreign equivalents) focus upon (i.) the proprietary design of the ProLung probe; (ii.) the computer algorithm used to drive the probe's action; and (iii.) the design of a group of algorithms or bioconductance profiles derived from the Company's clinical research. Other patents are pending. Solid practical protection is established by separating the point of testing with the ProLung System and the ProLung Test Report Server, which stores and serves algorithm data and prepares physician reports for distribution.

Management Experience

The Company is led by Steven C. Eror, a bio-entrepreneur with 40 years of collective experience in the areas of product commercialization, venture strategy, basic research, clinical product development, business development, M&A, IPO and regulatory affairs. The Company's advisory team features world opinion leaders in lung cancer management with relevant experience in healthcare, biotechnology, and operations at firms and institutions such as Pharmadigm, PPD Pharmaco, MacroMed, the University of Utah School of Medicine and Intermountain Healthcare.

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[1] http://www.lung.org/lung-health-and-diseases/lung-disease-lookup/lung-cancer/learn-about-lung-cancer/lung-cancer-fact-sheet.html
[2] http://globocan.iarc.fr/Pages/fact_sheets_cancer.aspx
[3] http://www.cancer.org/acs/groups/content/@research/documents/document/acspc-047079.pdf
[4] http://seer.cancer.gov/statfacts/html/lungb.html